

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

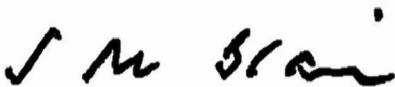
No. CE 662942
Issued To: **BNOS Meditech**
9 Fifth Avenue
Bluebridge Industrial Estate
Halstead
Essex
CO9 2SZ
United Kingdom

In respect of:

The design and manufacture of Meditech range of medical gas regulators, with and without therapy outlet. The design and manufacture of demand valves for use with medical gases including delivery systems for pre-mixed nitrous oxide and oxygen mixtures. The design and manufacture of the MicroVENT resuscitator, its derivatives and variants.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: **2016-12-05**

Date: **2018-10-19**

Expiry Date: **2023-10-19**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
05 December 2016	8630730	First issue. Transfer from another Notified Body.
Current	8998166	Renewal. Scope amended to include statement 'The design and manufacture of demand valves for use with medical gases including delivery systems for pre-mixed nitrous oxide and oxygen mixtures.'